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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

WITZ, JEAN C

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1651

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/023,753 | RUEPP, MICHEL | |
| | Examiner | Art Unit | |
| | Jean C. Witz | 1651 | |

-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6-9,11-13,16,17,19-22 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) 19-22 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6-9,11-13,16,17,25 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 08/765,623.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (Claims 1, 6-9, 11-13, 16-17 and 25-26) in paper received October 3, 2003 is acknowledged. The traversal is on the ground(s) that the search of other groups is not a significant burden. This is not found persuasive because search of inventions is not limited to the class and subclass of patents, but also involves extensive search of numerous databases of non-patent literature, which would involve a significant burden if the Examiner were to be required to search all the inventions. Since the restriction requirement is proper and the Examiner has determined the burden to search more than one invention to be significant, the requirement is therefore made FINAL.

Claims 19-22 and 24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 112

2. Claims 6, 9, 11, 13 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6 and 11 are multiply dependent upon Claims 1-4; however, Claims 2-4 have been canceled. Claims 6 and 11 lack antecedent basis for the canceled claims.

In Claim 9, the phrase “especially carbon dioxide” renders the claim vague and indefinite because the metes and bounds of the claim are not clear. See MPEP § 2173.05(d).

In Claim 13, the following terms are deemed vague and indefinite:

“vital lymphocytes” – it is unclear what property renders the lymphocytes “vital” – all in vivo lymphocytes are considered alive and therefore “vital”;

“Peyer’s plaques intestine)” – there appears to be a word or words missing and the presence of the ending parenthesis is unclear;

“sIGA” – this term is vague and indefinite since the meaning of the acronym is open to multiple interpretations;

“clear activation” – it remains unclear what level of activation is required to meet the limitation of the claim;

“creatinin” – this term is misspelled.

In Claim 16, it is unclear as to what is encompassed by the term “metabolic performance”.

Claim 26 is a method claim dependent upon Claim 6, a composition claim and therefore lacks antecedent basis in the previous claim. The phrase “especially dry extracts”, “further with” and “also in combination” renders the claim vague and indefinite because the metes and bounds of the claim are not clear. See MPEP § 2173.05(d).

3. Claims 7-8, 13, 16, 17 and 25-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for recitations of increases in polymorphonuclear granulocytes and suppressor lymphocytes and reductions in

creatinine, bilirubin, cholesterol and triglycerides, does not reasonably provide enablement for the physiological responses recited in the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In Claims 7-8, 13, 16, and 26, the claims require that the practice of the claimed method result in specific physiological responses such as an increase in the cell numbers of leukocytes, thrombocytes, erythrocytes and reduction in plasma levels of creatinine, uric acid, and glucose, etc.

Applicant appears to rely upon the results of tests set forth in the tables found on pages 23-25 of the specification. The data reported therein indicate the results of the claimed invention administered by itself and in conjunction with two chemotherapeutic agents, cyclophosphamide and furosemide. These tables fail to provide evidence of physiological results recited in the claims other than those described above. For example, the method of claim 13 recites that the administration of the putamen ovi results in an increase in the cell numbers of erythrocytes; however, the table on page 22 indicates that the administration of PO or Cys+PO resulted in no change of RBCs. Further, the physiological results described in sections (a), (b), (c) or (d) are not shown in the specification or contradicted by the results reported in the specification. Similarly, in claim 16, the results defined therein are not supported by the specification. In claim 17, cellular immunostimulation is claimed after immunosuppression after radiation or chemotherapeutic treatment. The results do not indicate that radiation occurred and it is further noted that with regard to furosemide, no immunosuppression occurred. In claim

25, the administration of PO did not result in any increase in RBCs. There are many causes of anemia and, other than a slight reduction due to furosemide administration, none are shown. Finally, no mention of treatment of depression occurs although claim 26 recites the administration of the claimed invention for the treatment of depression. As a result, there appears to be a high degree of unpredictability in the art with the use of this invention and therefore, the claims must be commensurate with the showing of the specification.

Claim Rejections - 35 USC § 101

Double Patenting

4. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re. Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

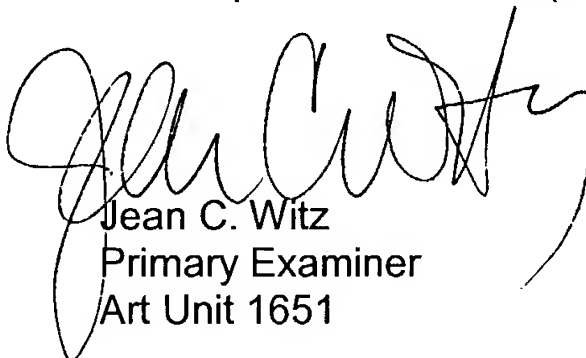
5. Claims 1, 6, 11 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 6 and 8 of prior U.S. Patent No. 6,344,217. This is a double patenting rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (571) 272-

0927. The examiner can normally be reached on 6:30 a.m. to 4:00 p.m. M-Th and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-0700.



Jean C. Witz
Primary Examiner
Art Unit 1651